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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,668	07/08/2003	Antonello Covacci	CHIR-0337	6533

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,668	COVACCI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/471,491.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *100803*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 08/31/06 and 07/08/2003.

Election

2) Acknowledgment is made of Applicants' election filed 01/15/07 in response to the species election requirement mailed 09/13/06. Applicants have elected the nucleotide sequence species of SEQ ID NO: 10. Because Applicants did not distinctly and specifically point out the supposed errors in the species election requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Applicants should note that due to the lack of prior art on an isolated polynucleotide from the nucleotide sequence of SEQ ID NO: 4 that comprises a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 10 as claimed, the search and examination has been extended to the next nucleotide sequence species, i.e., one that encodes the amino acid sequence of SEQ ID NO: 9.

Status of Claims

3) Claims 1-37 have been canceled via the amendment filed 07/08/03.

New claims 38-62 have been added via the amendment filed 07/08/03.

Claims 38-62 are pending and are under examination. An Action on the Merits for these claims is issued.

Sequence Listing

4) Acknowledgment is made of Applicants' raw Sequence Listing which has been entered on 07/29/03.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' information disclosure statement filed 10/08/03. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

6) This application is a Divisional application of SN 09/410,835, filed 10/11/1999, *now*

abandoned, which is a continuation of application SN 08/471,491, filed 06/06/95, now US patent 6,090,611, which is a Divisional application of SN 08/256,848, filed 10/21/94, now abandoned, which is a national stage application of PCT/EP93/00472, filed 03/02/93 and PCT/EP93/00158, filed 01/25/93, which claim the priority benefit of the Italian application, SN FI 92A000052, filed 03/02/92.

Specification - Informalities

7) The instant specification is objected to for the following reasons:

(a) The amendment introduced to the first paragraph of the specification via the preliminary amendment filed 07/08/2003 does not accurately reflect the current issued status of the earlier filed application(s) as indicated above in italicized letters under 'Priority'. Amendment to the first paragraph of the specification is needed to reflect this.

(b) The sequences disclosed in Figure 3 are non-compliant with Sequence Rules. The drawing for Figure 3 includes a nucleotide sequence longer than ten nucleotides and amino acid sequences longer than four amino acids in length. Yet, the sequences are not identified by specific sequence identifiers (SEQ ID numbers) as required under 37 C.F.R 1.821 through 1.825. This was brought to Applicants' attention via the communication mailed 06/26/06. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

(c) The amendment filed 08/06/02 is objected to under U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment introduced to the paragraph bridging pages 3 and 4 of the instant specification via the amendment filed 07/08/03 includes the following new limitations:

The present invention provides cytotoxin polypeptides that exhibit substantially no toxicity, or substantially reduced toxicity. The present invention also provides CAI and heat shock polypeptides that exhibit no functional contribution to toxicity, or a substantially reduced functional contribution to toxicity.

Double Patenting

8) The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

9) Claims 38-44, 49-54, 55, 59 and 62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polynucleotide claimed in claims 39 and 40 of the co-pending application comprising a nucleotide sequence encoding a protein comprising the amino acid sequence of SEQ ID NO: 9, or a fragment of the amino acid sequence of SEQ ID NO: 5 comprising at least 11 amino acids of SEQ ID NO: 5, for example SEQ ID NO: 9, or a polypeptide that is immunologically identifiable by an antibody which reacts specifically with the *Helicobacter pylori* CAI antigen having SEQ ID NO: 5, anticipates the instantly claimed polynucleotide.

10) Claims 38-44, 49-54, 55, 59 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the recombinant polynucleotide comprising the recited

SEQ ID NO: 4 and encoding *H. pylori* CAI antigen comprising the recited SEQ ID NO: 5 that comprises the instantly recited SEQ ID NO: 9, or the recited fragment thereof, anticipates the instantly claimed polynucleotide.

Rejection(s) under 35 U.S.C. § 101

11) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

12) Claim 46 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 46, as written, does not sufficiently distinguish over a host cell as it exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. The claimed host cell is not an 'isolated host cell'. In view of the contemplation within the instant specification at pages 19 and 21 of a mammalian host cell comprising the nucleotide sequence, the claimed host cell reads on a human vaccinated with a DNA vaccine expressing an antigenic determinant of CAI polypeptide. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --An isolated-- as is supported in the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

13) Claims 48, 57, 58 and 62 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection

New claim 48 includes the limitation: 'polynucleotide comprising at least 15 contiguous nucleotides from nucleotide position 2776 to nucleotide position 3466 of the nucleotide sequence of SEQ ID NO: 4'. New claim 57 includes the limitation: 'encoding amino acid positions 748 to 977 of the amino acid sequence of SEQ ID NO: 5'. New claim 58 includes the limitation: 'polynucleotide comprising the contiguous nucleotides from nucleotide position 535 to nucleotide

position 3975 of the nucleotide sequence of SEQ ID NO: 4'. New claim 62 includes the limitation: 'polynucleotide comprises at least one nucleotide sequence of nucleotides ..... 2641-2676 of SEQ ID NO: 4, or nucleotides 2776-2811 of SEQ ID NO: 4'. However, there appears to be no descriptive support in the instant specification for these new limitations. Applicants have not pointed to specific parts of the specification that provide descriptive support for these limitations. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

14) Claims 41, 51, 42, 52, 56, 59 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claims 41 and 51 include the limitation: 'immunogenic derivative of a *Helicobacter pylori* cytotoxin-associated immunodominant (CAI) antigen'. New claims 42 and 52 include the limitation: 'polynucleotide encodes an immunogenic derivative of the *Helicobacter pylori* CAI antigen'. New claims 56 and 59 include the limitation: 'immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5'. New claims 56 and 59 include the new limitation: 'immunologically identifiable with the amino acid sequence of SEQ ID NO: 5'. However, there appears to be no descriptive support in the specification, as originally filed, for these limitations. Applicants have not pointed to specific parts of the specification that provide descriptive support for these limitations. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Lack of Enablement)

15) Claims 38, 41-44, 51-53, 56 and 59 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

Instant claims encompass an isolated polynucleotide comprising at least 15, 30, or 45 contiguous nucleotides from the nucleotide sequence of SEQ ID NO: 4, wherein said polynucleotide comprises at least one nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 9 or SEQ ID NO: 10, where said polynucleotide encodes 'an immunogenic fragment' or 'an immunogenic derivative' of a *Helicobacter pylori* cytotoxin-associated immunodominant (CAI) antigen having the amino acid sequence of SEQ ID NO: 5, or an 'immunogenic fragment or immunogenic derivative' of a *Helicobacter pylori* CAI antigen 'which is immunologically identifiable' with the amino acid sequence of SEQ ID NO: 5. A review of the specification indicates 'prophylactic (to prevent infection) or therapeutic (to treat disease after infection)' applications for the polypeptide encoded by the claimed polynucleotide. For example, see paragraph bridging pages 38 and 39 of the specification. Therefore, the recited polypeptide 'fragment' or 'derivative' should have the prophylactic ability to prevent *H. pylori* infection when administered before a subject acquires the infection, and the therapeutic ability to treat *H. pylori*

infection when administered after a subject acquires the infection. The instant specification on page 50, lines 15 and 16 indicates that the non-recombinant CAI polypeptide was used to immunize rabbits. However, five amino acid-long, ten amino acid-long, or fifteen amino acid-long fragments of the recited CAI polypeptide, or the recited immunogenic 'fragment' or 'derivative' having prophylactic or therapeutic capacity, each encoded by the claimed polynucleotide or recombinant polynucleotide, are not enabled. The precise structure of the polynucleotides encoding such CAI polypeptide fragments, derivatives, or derivatives identifiable with the amino acid sequence of SEQ ID NO: 5, are not disclosed for one of skill in the art to make and use the instantly claimed polynucleotide. There is no evidence within the instant invention that immunogenic 'derivatives', 'fragments', or 'derivatives immunologically identifiable with the amino acid sequence of SEQ ID NO: 5' were indeed made and tested for their *H. pylori* CAI-specific immunogenicity, and therapeutic or prophylactic capacity against *H. pylori*. Without an enabling disclosure, specific guidance, and a concrete demonstration, one of skill in the art cannot practice the invention as claimed. This is important because although sufficiently long fragments or derivatives of any polypeptide encoded by a polynucleotide are expected to be immunogenic, the retention of their immunospecificity, i.e., *H. pylori* CAI polypeptide-specificity, is not predictable. Predictability or unpredictability is one of the *Wands* factors to be considered while analysing for enablement. The prophylactic or therapeutic efficacy of any 5-mer, 10-mer, or 15-mer bacterial polypeptide antigen fragment, or a bacterial polypeptide antigen derivative, is not predictable. Without a precise disclosure and/or specific guidance, one of ordinary skill in the art cannot envisage which 5-mer, 10-mer, or 15-mer fragments or derivatives of the recombinant or non-recombinant CAI polypeptide encoded by the claimed polynucleotide contribute to *H. pylori* CAI polypeptide-specificity, immunological identifiability with SEQ ID NO: 5, and *H. pylori*-specific therapeutic and/or prophylactic capacity. Whether or not such fragments and derivatives have functional or biologic capacity to be immunospecific to *H. pylori* CAI polypeptide, or to be prophylactic and therapeutic against *H. pylori*, is unknown and unpredictable, and would have required considerable amount of undue experimentation. The state of the art at the time of the invention demonstrated that at least the instantly recited EPIYA (SEQ ID NO: 10) fragment from the encoded polypeptide is not immunospecific to *H. pylori* CAI polypeptide, but is present for example in non- *H. pylori* elements such as human general transcription factor IIE. See Figure 1 of Peterson *et al.* (*Nature* 354: 369-

373, 1991). Thus, it is unpredictable that retention of any 5, 10 or 15 contiguous amino acid residues or a derivative thereof encoded by any part of the claimed polynucleotide would yield a polypeptide fragment or derivative that would have the expected *H. pylori* CAI-specific immunogenic functions and the capacity to be immunologically identifiable with the amino acid sequence of SEQ ID NO: 5. Furthermore, Peterson's disclosure above is evidence that any unmodified or unsubstituted 5, 10 or any 15 contiguous amino acid-long fragment, let alone a modified derivative, from the polypeptide of SEQ ID NO: 5, would not be *H. pylori*-specific and would not be immunologically identifiable with SEQ ID NO: 5. Not a single 'derivative' comprising 5, 10, or 15 contiguous amino acids from the amino acid sequence of SEQ ID NO: 5 has been shown in the instant specification to be *H. pylori* immunospecific or identifiable with SEQ ID NO: 5. Therefore, given the lack of enabling disclosure and/or specific guidance, the lack of working examples, the state of the prior art with regard to the functional unpredictability, the breadth of the claims, and the quantity of experimentation necessary, undue experimentation would have been required by one of ordinary skill in the art to practice the invention. The claims are viewed as not meeting the enablement provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

16) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

17) Claims 41-43, 45, 46, 51-53, 56 and 59 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 41, 42, 51, 52, 56 and 59 are vague and indefinite in the recitation 'derivative', because it is unclear what is encompassed within the recitation 'derivative'. What constitutes a derivative, and how much of the CAI antigen's original structure has to be retained such that the resulting product can be considered as a 'derivative', is not clear. The metes and bounds of the structure encompassed in the limitation 'derivative' are indeterminate.

(b) Dependent claims 41, 42, 51, 52, 56 and 59 are vague, indefinite and confusing in the recitation 'polynucleotide of claim ...., wherein said polynucleotide encodes an immunogenic

fragment,' 'or 'an immunogenic derivative' of a or the *Helicobacter pylori* CAI antigen. The polynucleotide of the independent claim from which these claims depend from are required to comprise at least one nucleotide sequence that encodes the amino acid sequence SEQ ID NO: 9 or SEQ ID NO: 10. Does it mean that the polynucleotide claimed in the above-identified dependent claims encodes the recited immunogenic fragment or immunogenic derivative in addition to the amino acid sequence SEQ ID NO: 9 or SEQ ID NO: 10? Clarification/correction is requested.

(c) Claim 45 is vague and/or incorrect in the limitation: 'claims 38 or 44' as opposed to claim 38 or 44. To be consistent with the claim language used in claims 41, 51 and 62, it is suggested that Applicants replace the above-identified limitation with the limitation --claim 38 or 44--

(d) Claims 56 and 59 are vague and indefinite in the recitation 'derivative .... immunologically identifiable with the amino acid sequence of SEQ ID NO: 5', because it is unclear what is encompassed in this limitation. What does 'immunological identifiability' include or involve is unclear. What characteristics a fragment or a derivative should have in order to be 'immunologically identifiable' with the 'the amino acid sequence of SEQ ID NO: 5' is not clear.

(e) Claim 46 is indefinite because it lacks proper antecedent basis in the limitation: 'a vector of claim 45'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the vector of claim 45--.

(f) Claim 42 is vague, indefinite and confusing in the limitation: 'an immunogenic derivative'. Claim 42 depends from claim 41, which already includes the limitation of 'an immunogenic derivative'. Does it mean that 'an immunogenic derivative' recited in the dependent claim 42 is different from the one recited in claim 41?

(g) Claim 52 is vague, indefinite and confusing in the limitation: 'an immunogenic derivative'. Claim 52 depends from claim 51, which already includes the limitation of 'an immunogenic derivative'. Does it mean that 'an immunogenic derivative' recited in the dependent claim 52 is different from the one recited in claim 51?

(h) Claim 43 is vague, indefinite and confusing in the limitation: 'an immunogenic fragment'. Claim 43 depends from claim 41, which already includes the limitation of 'an immunogenic fragment'. Does it mean that 'an immunogenic fragment' recited in the dependent claim 43 is different from the one recited in claim 41?

(i) Claim 53 is vague, indefinite and confusing in the limitation: 'an immunogenic fragment'. Claim 53 depends from claim 51, which already includes the limitation of 'an immunogenic fragment'. Does it mean that 'an immunogenic fragment' recited in the dependent claim 53 is different from the one recited in claim 51?

(j) Claims 42, 43, 45, 46, 52 and 53 are rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

18) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in-
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

19) Claims 38-53, 55, 56 and 59-62 are rejected 35 U.S.C. § 102(e)(2) as being anticipated by Cover *et al.* (US 5,403,924, filed 10/13/1992 – Applicants' IDS) ('924).

Instant claims are not granted priority to the Italian priority application FI/92/A/52, filed 03/02/92, since 15, 30, or 45 nucleotide-long isolated polynucleotide encoding 5, 10 or 15 amino acid-long *H. pylori* CAI antigen respectively, is not supported by the priority document.

Cover *et al.* ('924) disclosed an isolated polynucleotide having the nucleotide sequence of SEQ ID NO: 1 comprising at least 15, 30 or 45 contiguous nucleotides from the instantly recited nucleotide sequence of SEQ ID NO: 4 wherein the polynucleotide comprises the nucleotide sequence, GAA TTC AAA AAT GGC AAA AAT AAG GAT TTC AGC AAG, which encodes the instantly recited amino acid sequence of SEQ ID NO: 9, i.e., Glu Phe Lys Asn Gly Lys Asn Lys Asp Phe Ser Lys, located at amino acid positions 748-759 of the amino acid sequence encoded by said SEQ ID NO: 1. Cover's ('924) isolated polynucleotide comprises at least 15 contiguous nucleotides from nucleotide position 2776 to 3466, or nucleotides 2776-2811 of the instantly recited nucleotide sequence of SEQ ID NO: 4, and encodes at least 15 contiguous amino acids, for example, Ala Leu Asn Glu Phe Lys Asn Gly Lys Asn Lys Asp Phe Ser Lys, from the instantly recited amino acid sequence of SEQ ID NO: 5. See SEQ ID NO: 1 and the amino acid sequence that it encodes that are depicted under 'Sequence Listing' in columns 25-34 of Cover *et al.* ('924). Although Cover *et al.*

('924) refer to their encoded polypeptide antigen as *H. pylori* tagA antigen, this antigen is the same as the Applicants' encoded *H. pylori* CAI antigen because of the above-described sequence identity. Cover *et al.* ('924) further taught the full length *tagA* gene, *tagA* probes, and a recombinant polynucleotide encoding a truncated recombinant tagA antigen which reacts with serum from *H. pylori*-infected patients, i.e., immunogenic fragment or immunologically identifiable derivative. See columns 11, 19 and 20; paragraph bridging columns 10 and 11; section 'Nucleic Acids' in columns 2 and 3; Figures; and Examples 1 and 3. Cover *et al.* ('924) taught an isolated polynucleotide encoding the polypeptide or an antigenic fragment thereof, a vector comprising the same, and a host cell comprising the vector. See abstract; claims; Figures; Example 1; and section 'Vectors and Hosts' in columns 4-6. Due to the 100% sequence identity explained above, Cover's ('924) isolated polynucleotide comprising a nucleotide sequence encoding the instantly recited amino acid sequence of SEQ ID NO: 9 is expected to be immunologically identifiable with the amino acid sequence, Ala Leu Asn Glu Phe Lys Asn Gly Lys Asn Lys Asp Phe Ser Lys, comprised within Applicants' SEQ ID NO: 5.

Claims 38-53, 55, 56 and 59-62 are anticipated by Cover *et al.* ('924) ('924).

Remarks

20) Claims 38-62 stand rejected.

21) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

22) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached

on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April, 2007

SD.

S. DEVI, PH.D.
PRIMARY EXAMINER